

# FDA Warns Consumers About Bacterially–Contaminated Miracle II Neutralizer and Gel

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FDA Warns Consumers About Unapproved and Bacterially–Contaminated  
Miracle II Neutralizer and Miracle II Neutralizer Gel Drug Products

Use of Products Could lead to Severe Infections

The Food and Drug Administration (FDA) is advising consumers not to use Miracle II Neutralizer and Miracle II Neutralizer Gel products manufactured by Tedco, Inc., in West Monroe, Louisiana because the products are bacterially contaminated and have not been proven to be safe and effective. Use of these products could pose a risk of serious adverse events such as infections, particularly in children, the elderly, and individuals with weakened immune systems who are particularly susceptible to illness.

"We will not tolerate the marketing of products that use deceptive and untruthful claims to lure consumers into potentially dangerous situations," said Margaret O'K. Glavin, FDA's Associate Commissioner for Regulatory Affairs. "We consider it a significant public health hazard when consumers are deliberately deceived into using potentially dangerous products that promise health benefits but deliver only risk of harm."

Tedco, Inc., promotes Miracle II Neutralizer for ophthalmic use (in the eyes), including treatment of cataracts and pink eye, and as an eyewash. FDA requires that all ophthalmic products be sterile. Due to the substantial risk posed by non–sterility, Miracle II Neutralizer

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should never be applied to the eyes.

Tedco, Inc., also markets Miracle II Neutralizer for other unapproved uses, including treatment of AIDS, cancer, Crohn's Disease, dermatitis, diaper rash, diabetes, ear ache, hemorrhoids, hives, gout, herpes, mouth ulcers, psoriasis, skin cancer, and yeast infection. The firm sells Miracle II Neutralizer Gel for many of the same unapproved uses, including diaper rash, diabetes, gout, psoriasis, and skin cancer.

Tedco, Inc., promotes its Miracle II products with claims such as, "Supreme technology has made possible for a perfect soap cleaner, deodorizer, natural insecticide and antibacterial product to be put on the market. This is the only product that is made in the world that can wash a newborn baby or clean up an oil spill and everything in between." Contrary to such claims, recent FDA testing of Miracle II Neutralizer and Miracle II Neutralizer Gel revealed bacterial contamination and poor manufacturing conditions.

Although Tedco, Inc., has been advised by FDA of the contamination found in its Miracle II Neutralizer and Miracle II Neutralizer Gel products, the firm has declined to voluntarily remove the products from the market.

A number of stores sell Miracle II Neutralizer and Miracle II Neutralizer Gel, and the products are distributed and sold worldwide and sold via the Internet. The products are packaged in 8 oz, 22 oz, and one–gallon size containers.

FDA urges consumers, health care providers, and caregivers to cease using and dispose of these products and report any adverse events related to these products to MedWatch, the FDA's voluntary reporting program at 1–800–FDA–1088; by FAX at 1–800–FDA–0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857–9787; or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

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<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01268.html>

posted by Lisa Ruby

<http://www.libertytothecaptives.net>

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